NORTH CAROLINA DEPARTMENT OF
ENVIRONMENT AND NATURAL RESOURCES

DIVISION OF RADIATION PROTECTION

June 27, 2000

JAMES B. HUNT JR.
GOVERNOR

BILL HOLMAN
SECRETARY

RICHARD M. FRY
DIRECTOR

R. L. Woodruff
USNRC Region II
Atlanta Federal Center
Suite 23T85
61 Forsyth Avenue
Atlanta, GA 30303

RE: MISADMINISTRATION AT NORTH CAROLINA BAPTIST HOSPITALS, INC.

Dear Mr. Woodruff:

Enclosed is a copy of all correspondence between the agency and North Carolina Baptist Hospitals regarding the gamma knife misadministration. This was classified as a misadministration pursuant to 15A NCAC 11 .0104(67)(e)(ii), greater than 10% prescribed dose.

Should you have any questions, please feel free to contact me.

Sincerely,

Sharn M. Jeffries, Health Physicist
Radioactive Materials Section

Enclosures

3825 BARRETT DR. RALEIGH, NORTH CAROLINA 27609-7221
PHONE 919-571-4141 FAX 919-571-4148
AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER - 50% RECYCLED/10% POST-CONSUMER PAPER

NORTH CAROLINA DEPARTMENT OF
ENVIRONMENT AND NATURAL RESOURCES

DIVISION OF RADIATION PROTECTION

June 27, 2000

JAMES B. HUNT JR.
GOVERNOR

BILL HOLMAN
SECRETARY

RICHARD M. FRY
DIRECTOR

Subhash Danak, MS, DABR, DABMP, RSO
NC Baptist Hospitals, Inc.
Radiation Safety
Medical Center Boulevard
Winston Salem, NC 27157

Dear Mr. Danak:

I have received the "Report of Misadministration" dated June 22, 2000. The information supplied appears to be sufficient to address the misadministration which occurred on June 20, 2000 for NCRAML 034-0158-8. A copy of the report will be maintained in your file and the incident may be reviewed during the next inspection of your facility.

The North Carolina Regulations for Protection Against Radiation (15A NCAC 11 .0350(c)) require that you, the licensee, maintain a record of each misadministration for at least five (5) years.

Sincerely,

Sharn M. Jeffries, Health Physicist
Radioactive Materials Section

3825 BARRETT DR. RALEIGH, NORTH CAROLINA 27609-7221
PHONE 919-571-4141 FAX 919-571-4148
AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER - 50% RECYCLED/10% POST-CONSUMER PAPER

WAKE FOREST UNIVERSITY
WAKE FOREST UNIVERSITY SCHOOL OF MEDICINE
WAKE FOREST UNIVERSITY BAPTIST MEDICAL CENTER

RADIATION SAFETY
ENVIRONMENTAL HEALTH AND SAFETY
WAKE FOREST UNIVERSITY SCHOOL OF MEDICINE
MEDICAL CENTER BOULEVARD
WINSTON-SALEM, NC 27157
TELEPHONE (336) 777-3180
FAX (336) 777-3101

June 22, 2000

RECEIVED
JUN 27 2000
RADIOACTIVE MATERIALS

Sharn Jeffries
Health Physicist
N.C. Department of Environment, Health and Natural Resources
Division of Radiation Protection

Dear Mr. Jeffries,

I am writing to inform you of a possible misadministration, which I reported to you yesterday (June 21, 2000) at 3:20 p.m. This was identified on June 20, 2000 at 8:00 p.m.

The information regarding the event is as follows:

License Name: North Carolina Baptist Hospitals, Inc.

Address: Medical Center Blvd.
Winston-Salem, NC 27157

Phone: 336/777-3181

License Number: 034-0158-8

Expiration Date: July 31, 2004

Unit: Leksell Gamma Unit
Model 23004B-2
Gamma Knife

Authorized User: Edward Shaw, MD
Radiation Oncology Department
WFUBMC
Medical Center Blvd
Winston-Salem, NC 27157
336/716-4981

Description of Event:
Date and time the event was discovered – June 20, 2000 / 8:00 p.m.
Date reported to the Radiation Protection Branch via telephone – June 21, 2000 / 3:20 p.m.

The patient was treated by Gamma Knife radiosurgery for 16 shots (isocenters) using the 8 mm collimator on June 20, 2000. Patient treatment started at 4:30 p.m. and proceeded until about 8:00 p.m. Treatment for shot number 16 was begun at approximately 7:30 p.m., June 20, 2000.

WAKE FOREST UNIVERSITY
WAKE FOREST UNIVERSITY SCHOOL OF MEDICINE
WAKE FOREST UNIVERSITY BAPTIST MEDICAL CENTER

RADIATION SAFETY
ENVIRONMENTAL HEALTH AND SAFETY
WAKE FOREST UNIVERSITY SCHOOL OF MEDICINE
MEDICAL CENTER BOULEVARD
WINSTON-SALEM, NC 27157
TELEPHONE (336) 777-3180
FAX (336) 777-3101

Shot number 16 had a prescription of 22.5 Gray at the 50% isodose line and required a timer setting of 7.6 minutes. A timer setting of 8.6 minutes for shot number 15 was used instead, delivering a total dose of 25.0 Gray instead of 22.5 Gray. Ratio of the timer settings (8.67 / 7.6) indicates a 13% overdose. Calculations on the treatment planning system show an 11% overdose. The 2% difference (11% vs 13%) occurs because other shots contribute a small amount of background dose to the location of Shot 16.

Cause: Shot 15 was difficult to reach due to a prohibited X coordinate. Since Shot 15 could not be reached, Shot 16 was set and initiated. The Authorized User set the timer and initiated treatment. As the time for Shot 16 ended, the Physicist observed that the elapsed time was summing to 8.6 minutes, which was in error with the time indicated by the plan protocol sheet. It was realized that the time for Shot 15 had been set instead of the time for Shot 16. When the Authorized User had set the time for Shot 16 the timer setting was not verified a second time by either member of the treatment team.

Notification: After the completion of Shot 16, the Authorized User informed the patient of the overdose. The Authorized User has written a letter to inform the referring physician of the overdose.

Action Taken to Prevent Further Occurrences: Gamma Knife Authorized User and Operators will be reminded that all timer settings must be verified a second time prior to initiation of treatment.

Clinical Consequences: The Authorized User states that no consequences are expected, based on the small volume being treated (8mm collimator) and the tolerance dose for small volume radiosurgery targets.

An internal report shall be made including the names of all individuals involved in the event, the referring physician, the attending physician, the patient's name and social security number and medical record number. This report will also include a detailed description of the event, the steps taken to prevent future occurrence and the information provided in this report. These records will be kept on file for ten (10) years.

Thank you for your attention to this matter and please do not hesitate to contact me if I can provide you any further information.

Sincerely,

Subhash Danak, MS, DABR, DABMP
Radiation Safety Officer

CC: Carol Boles, MD, Chair RSC
J. Daniel Bourland, Ph.D., DABR, Section Head, Physics, Radiation Oncology
Ed Shaw, MD, Chair, Radiation Oncology
David Brown, Director, Environmental Health and Safety